GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:3384
ANSWERED ON:11.12.2002
CLEARANCE TO BIO-TECH UNITS IN AP
DAGGUBATI RAMANAIDU

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) the number of applications filed by leading Bio-Tech units in the State of Andhra Pradesh for clearance by the Drugs Controller General of India (DCGI) during the last three years;

(b) the number of applications cleared by the DCGI during each of the last three years and during the current year;

(c) whether the Union Government have received any request from Andhra Pradesh Government for early clearance of applications by DCGI;

(d) if so, the details thereof; and

(e) the action taken by the Government thereon?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI A. RAJA)

(a) & (b) : Before approving indigenously manufactured Bio-tech products, the proposal is required to be gone through various stages like Clearance of Recombinant Committee for Genetic Manipulation (under Department of Bio- Technology),Validation of test report by CDL, Kasauli/Kolkata, Conduction of Clinical Trial, Clearance of Expert Committee constituted by Ministry of Health for r-DNA based Therapeutics, Clearance of Genetic Engineering Approval Committee (GEAC) under Ministry of Environment, verification of manufacturing facility as per GMP norms etc.

The details indicating the number of applications filed by the leading Bio-Tech units in the State of Andhra Pradesh and the corresponding year by which the approval accorded by the office of DCG (I) in respect of Recombinant products proposed to be indigenously manufactured during the last three years and current year are at Annexure.

(c),(d) &(e): Shri B.P.Achraya, Secretary to Government A.P. through a copy of letter from Hon`ble Chief Minister of Andhra Pradesh addressed to the Hon`ble Union Minister for Health and Family Welfare dated 03.08.2001, requested that suitable instruction be issued to DCG(I) for an early disposal of the pending proposal pertaining to leading biotech units in the States and not to take credence of certain allegations and counter allegations by certain prominent Bio-Tech companies in the State of Andhra Pradesh.

The office of DCG(I) approved the three proposals pertaining to biotech products for units existing in the State of Andhra Pradesh, after completion of statutory requirements. Permission for conducting clinical trial have been accorded in respect of remaining three applications i.e. (i) r-streptokinase of M/s Shantha Biotech Pvt. Ltd., Hyderabad,(ii) r-streptokinase of M/s Bharat Biotech (I) Limited, Hyderabad and (iii) Interferon alpha 2b of M/s Dr. Reddy`s Lab, Hyderabad.

ANNEXURE

Year	No.of Applications Received	Year in which formalities completed	required the office	Year in which proposal cleared by DCG(I)
1999	1	Dec.2001		Feb.2002
2000	4. One proposal in the year April 2001 and second proposal in the year March 2002. In third proposal the clinical trial is being undertaken by the	One proposal in the year June 2001 and second proposal cleared in		One proposal in the

	applicant. In the fourth proposal, the report of clinical trial received on 30.6.2002 and GEAC approval is awaited.	the	year March 2002.
2001	2. In both the proposals the clinical trial is being undertaken by the applicant.		